Remarks

A. Pending Claims

Claims 1- 6, 8 - 28, 53, 75, 97, 116, and 140 are pending in the application. Claims 1- 6, 8 - 28, 53, 75, 97, 116, and 140 have been rejected. Claims 3 and 4 have been cancelled. Claims 1, 28, 53, 97, and 116 have been amended.

B. The Claims Do Comply With The Written Description Requirement Pursuant To 35 U.S.C. § 112 First Paragraph

Claims 97 and 116 were rejected pursuant to 35 U.S.C. §112 as failing to comply with the written description requirement. Applicant respectfully disagrees.

The Office Action states:

> Claims 97 and 116 recite wherein the reinforcing member is positioned within the heart "subsequent to a cardiovascular event prior to substantial deformation." However, this limitation is not supported by the specification, which states that the reinforcing member is positioned after a cardiovascular event so that the possibility of ventricular deformation is lessened (see paragraph [0151]). Therefore, the instant specification only supports where ventricular deformation is lessened, not where the apparatus is positioned prior to substantial deformation.

Applicant respectfully disagrees with the rejection; however claim 97 has been amended to expedite prosecution of the present application.

Claim 116 describes a combination of features including, but not limited to, the feature of: "attaching a reinforcing element to a region of an endocardial surface of the ventricle subsequent to a cardiovascular event prior to substantial ventricular deformation."

The specification states:

If reinforcing element 908 is implanted soon after infarction (as depicted in FIG. 11) the remodeling resulting from myocardial infarction may be inhibited and/or substantially lessened. In some embodiments, reinforcing element 908 may have a shape and/or size substantially mimicking infarcted region 906. **In certain embodiments, reinforcing element 908 may be positioned in a ventricle soon after a myocardial infarction and before the ventricle has had an opportunity to begin remodeling itself**; therefore, the reinforcing element may be of a shape and/or size of a portion of the existing ventricle. The size and/or shape of infarcted tissue may be obtained, for example, by analyzing delayed hyperenhanced cardiac MRI images. Cardiac analysis software such as SIMON (Chase Medical, Richardson, Texas) is commercially available and able to perform such analysis. Cardiac analysis software, such as SIMON, may assist in analyzing the size and/or shape of the scar. Analysis software may assess the location of the scar with respect to other cardiac structures (e.g., papillary muscles, mitral valve, aortic valve, and/or septum). (emphasis added). (Specification, page 26, lines 17-29).

The specification further states:

Certain embodiments of a reinforcing element inhibit further deformation of a ventricle. **Methodology and apparatus embodiments that inhibit further deformation of a ventricle require a user to position a reinforcing element as soon as is feasible after a cardiovascular event (e.g., a myocardial infarction) in a subject**. The possibility of ventricular deformation is lessened by positioning a reinforcing element in a ventricle as early as possible. Early positioning of the reinforcing element may increase the beneficial impact of the reinforcing element in inhibiting further deformation. Inhibiting further deformation may not be enough, however, in cases where moderate to extensive ventricular deformation has already occurred. (emphasis added). (Specification, page 36, lines 5-13).

Applicant submits there is support for the amendment to the claims in the specification. Applicant respectfully request the rejection to claims 97 and 116 be removed.

C. **The Claims Are Not Anticipated By Khairkhahan Pursuant To 35 U.S.C. § 102(e)**

Claims 1-6, 8-28, 53, and 140 were rejected pursuant to 35 U.S.C. §102 (e) as being anticipated by U.S. Patent Application Publication No. 2002/0111647 A1 to Khairkhahan et al. (herein after "Khairkhahan"). Applicant respectfully disagrees.

The standard for "anticipation" is one of fairly strict identity. To anticipate a claim of a patent, a single prior source must contain all the claimed essential elements. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q.81, 91 (Fed. Cir. 1986); In re Donahue, 766 F.2d 531,226 U.S.P.Q. 619,621 (Fed. Cir. 1985).

The Office Action states:

> With regard to claims 1, 5, and 15 Khairkhahan discloses an apparatus comprising a reinforcing element (11) configured to reinforce a portion of an endocardial surface (see entire document; Figure 1). The element (11) is movable between a reduced, first predetermined shape and an expanded, second predetermined shape ([0060]). An adjustment mechanism is utilized to expand the device while in a patient's body so that the reinforcing element is configured to change from the first shape to the second while in a ventricle of the patient's heart ([00796]). The adjustment mechanism is further disclosed as a pullwire that is activated by a user ([0076]). Therefore, there inherently exists an infinite number of cross-sectional profiles of the reinforcing element between the fully reduced, first predetermined shape and the fully expanded, second predetermined shape so that user is able to adjust the adjustment mechanism to a third shape.
>
> Although Khairkhahan does not specifically disclose the reinforcing element for use in an endocardial surface of a ventricle, specifically scar tissue, this is an intended use phrase and therefore given minimal patentable weight. The examiner's position is supported by law, which holds that "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation." Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) and MPEP 2111.02.

Applicant respectfully submits that Khairkhahan does not appear to teach or suggest the combination of features in claims 1-6, 8-28, 53, and 140.

Amended claim 1 describes a combination of features including, but not limited to, the feature of: "wherein the second predetermined shape is configured to reinforce at least a portion of an endocardial surface of a ventricle of the human heart during use such that the portion of the endocardial surface is inhibited from expanding while still allowing normal contraction and expansion during a cardiac cycle of the heart." Applicant submits that amendments to the claim are fully supported and do not require a new search.

Amended claim 28 describes a combination of features including, but not limited to, the feature of: "wherein the reinforcing element is configured to attach to a portion of an endocardial surface of the heart to inhibit expansion of an average of an endocardial surface over a cardiac cycle of the heart, while still allowing normal contraction and expansion of the heart during a cardiac cycle." Applicant submits that amendments to the claim are fully supported and do not require a new search.

Amended claim 53 describes a combination of features including, but not limited to, the feature of: "wherein the reinforcing element is configured to inhibit expansion of an average of an endocardial surface over a cardiac cycle of the heart during use, while still allowing normal contraction and expansion of the heart during a cardiac cycle." Applicant submits that amendments to the claim are fully supported and do not require a new search.

Khairkhahan discloses:

> [0059] In use, the occlusion device 10 is preferably positioned within a tubular anatomical structure to be occluded such as the left atrial appendage. In a left atrial appendage application, the occluding member 11 is positioned across or near the opening to the LAA and the stabilizer 194 is positioned within the LAA. The stabilizer 194 assists in the proper

location and orientation of the occluding member 11, as well as resists compression of the LAA behind the occluding member 11. The present inventors have determined that following deployment of an occluding member 11 without a stabilizer 194 or other bulking structure to resist compression of the LAA, normal operation of the heart may cause compression and resulting volume changes in the LAA, thereby forcing fluid past the occluding member 11 and inhibiting or preventing a complete seal. Provision of a stabilizer 194 dimensioned to prevent the collapse or pumping of the LAA thus minimizes leakage, and provision of the barbs facilitates endothelialization or other cell growth across the occluding member 11.

[0060] The stabilizer 194 is preferably movable between a reduced cross-sectional profile for transluminal advancement into the left atrial appendage, and an enlarged cross-sectional orientation as illustrated to fill or to substantially fill a cross-section through the LAA. The stabilizing member may enlarge to a greater cross section than the (pre-stretched) anatomical cavity, to ensure a tight fit and minimize the likelihood of compression. One convenient construction includes a plurality of elements 196 which are radially outwardly expandable in response to axial compression of a distal hub 191 towards a proximal hub 16. Elements 196 each comprise a distal segment 198 and a proximal segment 202 connected by a bend 200. The elements 196 may be provided with a bias in the direction of the radially enlarged orientation as illustrated in FIG. 2, or may be radially expanded by applying an expansion force such as an axially compressive force between distal hub 191 and proximal hub 16 or a radial expansion force such as might be applied by an inflatable balloon. Elements 196 may conveniently be formed by laser cutting the same tube stock as utilized to construct the distal hub 191, proximal hub 16 and frame 14, as will be apparent to those of skill in the art in view of the disclosure herein. Alternatively, the various components of the occlusion device 10 may be separately fabricated or fabricated in subassemblies and secured together during manufacturing. (Khairkhahan, page 4).

Khairkhahan appears to teach or suggest an occlusion device which functions to resist compression and prevent the collapse of a tubular anatomical structure wherein the occlusion device is positioned. Khairkhahan does not appear to teach or suggest the combination of features in the claims, including but not limited to "wherein the second predetermined shape is configured to reinforce at least a portion of an endocardial surface of a ventricle of the human heart during use such that the portion of the endocardial surface is inhibited from expanding while still allowing normal contraction and expansion during a cardiac cycle of the heart," or "wherein the reinforcing element is configured to attach to a portion of an endocardial surface of

the heart to inhibit expansion of an average of an endocardial surface over a cardiac cycle of the heart, while still allowing normal contraction and expansion of the heart during a cardiac cycle," or "wherein the reinforcing element comprises: a plurality of conduits that form the predetermined shape during use; and at least one elongated member positionable in one or more of the plurality of conduits, wherein at least one such elongated member is configured to at least partially extend beyond a distal end of the corresponding conduit when activated to engage the portion of the endocardial surface."

In addition, amended claim 28 describes a combination of features including, but not limited to, the feature of: "a plurality of conduits that form the first predetermined shape, the second predetermined shape, or the first predetermined shape and the second predetermined shape; and at least one elongated member positionable in one or more of the plurality of conduits, wherein at least one such elongated member is configured to at least partially extend beyond a distal end of the corresponding conduit and to engage the portion of the endocardial surface when activated." Applicant submits that amendments to the claim are fully supported and do not require a new search.

In addition, amended claim 53 describes a combination of features including, but not limited to, the feature of: "wherein the reinforcing element comprises: a plurality of conduits that form the predetermined shape during use; and at least one elongated member positionable in one or more of the plurality of conduits, wherein at least one such elongated member is configured to at least partially extend beyond a distal end of the corresponding conduit when activated to engage the portion of the endocardial surface." Applicant submits that amendments to the claim are fully supported and do not require a new search.

Khairkhahan does not appear to teach or suggest an elongated member positionable inside of a conduit, wherein the elongated member is extendable out of a distal end of the conduit such that the elongated member engages an endocardial surface (e.g., an example of an embodiment of such an elongated member positionable in a conduit is depicted in FIGS. 16 and 17).

Applicant submits, that many of the claims dependent on claim 1 are separately patentable. At least a few of the separately patentable dependent claims are listed below by way of example.

The Office Action states:

> With regard to claim 140, as shown in Figure 1, the shape of the reinforcing member is similar to a shape and size of a portion of the left ventricle.

Claim 140 includes, but is not limited to, the feature of: "wherein the third shape is similar to a shape and size of at least a portion of an appropriate left ventricle." The features of claim 140, in combination with the features of independent claim 1, do not appear to be taught or suggested by the prior art.

The specification discloses:

> In some embodiments, a shaping device may be pre-shaped to generally model the appropriate volume and shape of the left ventricle, as is depicted in FIG. 2a. Shaping device 200 may be used as a guide in reforming the left ventricle so that the reconstructed heart may be formed closer to the size and shape of the pre-enlarged heart. Consequently, the heart performs better post operatively than with conventional methods. As illustrated in FIG. 2a, shaping device 200 may be conical or "tear drop" in shape. The length of shaping device 200 may vary with each patient and will typically be a function of the volume selected for the shaping device. The size, shape, and/or volume of shaping device 200 may vary according to individual patient specific needs. Shaping device 200 may be designed and manufactured for a specific patient's needs. In some embodiments, shaping device 200 may be manufactured in a variety of sizes, shapes, and/or volumes, from which a user may select an appropriate shaping device for a specific patient. Depending on the patient, the length may be between about three inches to about four inches to generally match the length of the pre-enlarged left ventricle. A doctor may select the appropriate volume for the shaping device by estimating the volume of the pre-enlarged left ventricle. Such selection procedures and shaping devices are discussed in U.S. patent application serial no. 09/864,510, filed on

May 24, 2001 by the inventors, which is hereby incorporated by reference into this application.

Khairkhahan appears to teach or suggest an occlusion device which functions to resist compression and prevent the collapse of a **tubular** anatomical structure wherein the occlusion device is positioned. Khairkhahan does not appear to teach or suggest the combination of features in the claims, including but not limited to "wherein the third shape is similar to a shape and size of at least a portion of an appropriate left ventricle."

Applicant requests removal of the anticipation rejection of claims 1-6, 8-28, 53, and 140.

D. The Claims Are Not Anticipated By Macoviak Pursuant To 35 U.S.C. § 102(e)

Claims 1, 16, and 22 were rejected pursuant to 35 U.S.C. §102 (e) as being anticipated by U.S. Patent Application Publication No. 2002/0143362 A1 to Macoviak et al. (herein after "Macoviak"). Applicant respectfully disagrees.

The Office Action states:

> With regard to claim 1, Macoviak discloses an apparatus comprising a reinforcing element (114) configured to reinforce a portion of an endocardial surface (see entire document; Figure 2). The element (114) is movable between a reduced, first predetermined shape and an expanded, second predetermined shape ([0038]; Figures 2 and 3). An adjustment mechanism is utilized to expand the device while in a patient's body so that the reinforcing element is configured to change from the first shape to the second while in a ventricle of the patient's heart ([0043]). Therefore, there inherently exists an infinite number of cross-sectional profiles of the reinforcing element between the fully reduced, first predetermined shape and the fully expanded, second predetermined shape so that user is able to adjust the adjustment mechanism to a third shape.

Applicant respectfully submits that Macoviak does not appear to teach or suggest the combination of features in claim 1.

Claim 1 describes a combination of features including, but not limited to, the feature of: "wherein the second predetermined shape of the reinforcing element is configured to attach to a portion of the endocardial surface of the ventricle of the heart."

Macoviak discloses:

> [0008] In keeping with the foregoing discussion, the present invention takes the form of a catheter or cannula having a cerebral embolic protection assembly (CEPA) mounted on an elongated tubular catheter shaft. The elongated tubular catheter shaft is adapted for introduction into a patient's ascending aorta either by a peripheral arterial approach or by a direct aortic puncture. The CEPA has an undeployed state where it is compressed or wrapped tightly around the catheter shaft and a deployed state where it expands to the size of the aortic lumen. The CEPA assembly can be passively or actively deployed. Various mechanisms are disclosed for both passive and active deployment. (Macoviak, page 1).

Macoviak further discloses:

> [0011] In use, the CEPA is introduced into the patient's aorta, either by a peripheral arterial approach or by direct aortic puncture, with the CEPA in a collapsed state. The CEPA is advanced across the aortic arch and into the arch and ascending aorta. When a portion of the CEPA is positioned in the ascending aorta between the aortic valve and the brachiocephalic artery, the CEPA is either actively or passively deployed. The position of the catheter and the deployment state of the CEPA may be monitored using fluoroscopy, ultrasound, transesophageal echography (TEE) or aortic transillumination using visible, infrared or near infrared light. Once the CEPA is deployed, oxygenated blood may be infused into the aorta through the perfusion lumen or alternatively the beating heart may supply all the blood or a combination of both. Any potential emboli are captured or rerouted by the CEPA and are thereby prevented from entering the neurovasculature. After use, the CEPA is returned to the collapsed position and the catheter is withdrawn from the patient. Methods according to the present invention are described using the aortic catheter for occluding and compartmentalizing or partitioning the patient's aortic lumen and for performing selective filtered aortic perfusion. (Macoviak,

page 1).

Macoviak appears to teach or suggest cerebral embolic protection assembly (CEPA) mounted on an elongated tubular catheter shaft temporarily positionable in a patient's aorta for the duration of a procedure after which the CEPA is collapsed and withdrawn from the patient. Macoviak does not appear to teach or suggest the combination of features in the claims, including but not limited to "wherein the second predetermined shape of the reinforcing element is configured to attach to a portion of the endocardial surface of the ventricle of the heart."

Applicant submits, that many of the claims dependent on claim 1 are separately patentable.

The Office Action further states:

> With regard to claim 16, the reinforcing element comprises struts (118), which clearly overlap the instantly claimed conduits ([0042]; Figure 2). Shaft (104) is positioned within the conduits and extends distally beyond the conduits as shown in Figure 2 ([0042]). Therefore, shaft (104) clearly overlaps the instantly claimed elongated member.

Applicant respectfully submits that Macoviak does not appear to teach or suggest the combination of features in claim 16.

Claim 16 describes a combination of features including, but not limited to, the feature of: "a plurality of conduits that form the first predetermined shape, the second predetermined shape, or the first predetermined shape and the second predetermined shape; and at least one elongated member positionable in one or more of the plurality of conduits, wherein at least one such elongated member is configured to at least partially extend beyond a distal end of the corresponding conduit and to engage the portion of the endocardial surface when activated."

Macoviak discloses:

[0042] The embolic filter assembly 102 is movable between a collapsed state, as shown in FIG. 3, and an expanded or deployed state, as shown in FIGS. 1 and 2. The filter screen 112 may be attached directly to the catheter shaft 104 and it may constitute the entire embolic filter assembly 102, particularly if the filter screen 112 is made of a resilient or semirigid fabric that has enough body to be self-supporting in the deployed state. Generally, however, the embolic filter assembly 102 will also include a filter support structure 114, particularly if a highly flexible or flaccid material is used for the filter screen 112. The filter support structure 114 attaches and supports the filter screen 112 on the catheter shaft 104. In the illustrative embodiment of FIGS. 1-3, the filter support structure 114 is constructed with an outer hoop 116 and a plurality of struts 118 which extend approximately radially from a ring-shaped hub 126 that is mounted on the catheter shaft 104. In this case four struts 118 are shown, however, two, three or more struts 118 may be used. The open distal end 122 of the filter screen 112 is attached to the outer hoop 116 and the proximal end 120 of the filter screen 112 is sealingly attached to the catheter shaft 104. When the embolic filter assembly 102 is deployed, the outer hoop 116 of the filter support structure 114 holds the open distal end 122 of the filter screen 112 against the inner wall of the aorta, as shown in FIG. 1. To accommodate most normal adult aortas, the outer hoop 116 of the filter support structure 114 and the distal end 122 of the filter screen 112 have a diameter of approximately 2.5 to 4 cm, plus or minus 0.5 cm. Larger and smaller diameter filter support structures 114 may be made to accommodate patients with distended or Marfan syndrome aortas or for pediatric patients. (Macoviak, page 3).

Macoviak appears to teach or suggest solid support struts 118 attached to a ring-shaped hub 126 through which shaft 104 passes through. Macoviak does not appear to teach or suggest an elongated member positionable inside of a conduit, wherein the elongated member is extendable out of a distal end of the conduit such that the elongated member engages an endocardial surface. Macoviak does not appear to teach or suggest the combination of features in the claims, including but not limited to "wherein the second predetermined shape of the reinforcing element is configured to attach to a portion of the endocardial surface of the ventricle of the heart."

The Office Action further states:

With regard to claim 22, as shown in Figure 2, the conduits (118) radiate from a center region.

Applicant respectfully submits that Macoviak does not appear to teach or suggest the combination of features in claim 22.

Claim 22 describes a combination of features including, but not limited to, the feature of: "wherein at least two of the conduits radiate from a center region." Macoviak appears to teach or suggest solid support struts 118 attached to a ring-shaped hub 126 through which shaft 104 passes through. Macoviak does not appear to teach or suggest a conduit as explained in regards to claim 22. Macoviak does not appear to teach or suggest the combination of features in the claims, including but not limited to "wherein at least two of the conduits radiate from a center region."

Applicant requests removal of the anticipation rejection of claims 1, 16, and 22.

E. <u>The Claims Are Not Anticipated By Whayne Pursuant To 35 U.S.C. § 102(e)</u>

Claims 97 and 116 were rejected pursuant to 35 U.S.C. §102 (e) as being anticipated by U.S. Patent No. 6,887,192 B1 to Whayne et al. (herein after "Whayne"). Applicant respectfully disagrees.

The Office Action states:

> Whayne discloses the method of placing a reinforcing member within a ventricle of human heart (see entire document; column 4, lines 25-35; Figure 1). The member is positioned subsequent to a cardiovascular event and prior to substantial ventricular deformation (column 3, line 56 through column 4, line 6; column 4, lines 34-36). The reinforcing member is then attached to the heart through anchors or pins, which are releasable attachments (column 6, lines 30-34; column 12, lines 47-51). Once attached, the expansion of an average of an endocardial surface over a cardiac cycle is inhibited (column 4, lines 30-34). Furthermore, the reinforcing member is preshaped to match the ventricle

(column 11, lines 20-22). Therefore, a portion of the natural contour of the ventricle is maintained with the reinforcing member.

Applicant respectfully submits that Whayne does not appear to teach or suggest the combination of features in claims 97 and 116.

Amended claim 97 describes a combination of features including, but not limited to, the feature of: "adjusting a dimension of at least a portion of the reinforcing element using an adjustment mechanism such that a dimension of a least a portion of the ventricle is changed." Applicant submits that amendments to the claim are fully supported and do not require a new search.

Amended claim 116 describes a combination of features including, but not limited to, the feature of: "extending one or more elongated members of the reinforcing element beyond a distal end of one or more conduits of the reinforcing element to releasably attach the reinforcing element to a portion of the endocardial surface such that deformation of the portion of the endocardial surface is inhibited." Applicant submits that amendments to the claim are fully supported and do not require a new search.

Whayne discloses:

> FIG. 12A shows a support structure 20 that incorporates an anchor 52 designed to penetrate into tissue. Anchor pins 54 extend radially away from anchor 52 at acute angles to maintain the position of the anchor within the tissue surface, once positioned. Anchor pins 54 may extend from the anchor in curves as shown in FIG. 12B, along lines as shown in FIG. 12C, or in other orientations. As shown in FIG. 12D, support structure 20 is secure to the tissue surface after anchor 52 is inserted through the first heart surface (epicardium 60 or endocardium 58) and anchor pins 54 are constrained from axial movement by the myocardium 56.
>
> Alternatively, the anchor may be inserted past the first heart surface (epicardium 60 or endocardium 58), through the myocardium 56, and past the second heart surface (endocardium 58 or epicardium 60) such that the anchor pins are constrained by the second heart surface. As shown in FIG. 12D, a tissue interface 18 spaces the support structure from the

> tissue surface, as will be described in detail below; even so, tissue interface 18 must enable insertion of the anchor during positioning and securing of the support structure. (Whayne, column 12, lines 47-67).

Whayne does not appear to teach or suggest the combination of features in the claims, including but not limited to "adjusting a dimension of at least a portion of the reinforcing element using an adjustment mechanism such that a dimension of a least a portion of the ventricle is changed," or "extending one or more elongated members of the reinforcing element beyond a distal end of one or more conduits of the reinforcing element to releasably attach the reinforcing element to a portion of the endocardial surface such that deformation of the portion of the endocardial surface is inhibited."

Applicant requests removal of the anticipation rejection of claim 97 and 116.

F. <u>The Claims Are Not Obvious Over Macoviak Pursuant To 35 U.S.C. § 103(a)</u>

Claims 27 and 75 were rejected under 35 U.S.C. 103(a) as obvious over Macoviak. Applicant respectfully disagrees with the rejection.

In order to reject a claim as obvious, the Examiner has the burden of establishing a *prima facie* case of obviousness. *In re Warner et al.*, 379 F.2d 1011, 154 U.S.P.Q. 173, 177-178 (C.C.P.A. 1967). To establish a *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974), MPEP § 2143.03.

The Office Action states:

> Macoviak discloses a reinforcing member having a first and second predetermined shape. The reinforcing member comprises conduits (118) disposed over shaft (114). The shaft is further disclosed as having a guidewire lumen ([0058]). Although Macoviak does not specifically teach a guidewire within the lumen, it would have been obvious to one of ordinary skill at the time of the invention since it is known in the art for

guidewires to be placed within a guidewire lumen and extend distally beyond the device in order to steer/guide the device to the target site.

Applicant respectfully submits that Macoviak does not appear to teach or suggest the combination of features in claims 27 and 75.

Claim 75 describes a combination of features including, but not limited to, the feature of: "wherein the reinforcing element is configured to change to a second predetermined shape and attach to a portion of the endocardial surface of a left or right ventricle of the heart, and wherein the reinforcing element is configured to inhibit expansion of an average of an endocardial surface over a cardiac cycle, while still allowing normal contraction and expansion of the heart during a cardiac cycle."

Macoviak discloses:

[0008] In keeping with the foregoing discussion, the present invention takes the form of a catheter or cannula having a cerebral embolic protection assembly (CEPA) mounted on an elongated tubular catheter shaft. The elongated tubular catheter shaft is adapted for introduction into a patient's ascending aorta either by a peripheral arterial approach or by a direct aortic puncture. The CEPA has an undeployed state where it is compressed or wrapped tightly around the catheter shaft and a deployed state where it expands to the size of the aortic lumen. The CEPA assembly can be passively or actively deployed. Various mechanisms are disclosed for both passive and active deployment. (Macoviak, page 1).

Macoviak further discloses:

[0011] In use, the CEPA is introduced into the patient's aorta, either by a peripheral arterial approach or by direct aortic puncture, with the CEPA in a collapsed state. The CEPA is advanced across the aortic arch and into the arch and ascending aorta. When a portion of the CEPA is positioned in the ascending aorta between the aortic valve and the brachiocephalic artery, the CEPA is either actively or passively deployed. The position of the catheter and the deployment state of the CEPA may be monitored using fluoroscopy, ultrasound, transesophageal echography (TEE) or aortic transillumination using visible, infrared or near infrared light. Once the CEPA is deployed, oxygenated blood may be infused into the aorta

> through the perfusion lumen or alternatively the beating heart may supply all the blood or a combination of both. Any potential emboli are captured or rerouted by the CEPA and are thereby prevented from entering the neurovasculature. After use, the CEPA is returned to the collapsed position and the catheter is withdrawn from the patient. Methods according to the present invention are described using the aortic catheter for occluding and compartmentalizing or partitioning the patient's aortic lumen and for performing selective filtered aortic perfusion. (Macoviak, page 1).

Macoviak appears to teach or suggest cerebral embolic protection assembly (CEPA) mounted on an elongated tubular catheter shaft temporarily positionable in a patient's aorta for the duration of a procedure after which the CEPA is collapsed and withdrawn from the patient. Macoviak does not appear to teach or suggest the combination of features in the claims, including but not limited to "wherein the reinforcing element is configured to change to a second predetermined shape and attach to a portion of the endocardial surface of a left or right ventricle of the heart, and wherein the reinforcing element is configured to inhibit expansion of an average of an endocardial surface over a cardiac cycle, while still allowing normal contraction and expansion of the heart during a cardiac cycle."

In addition, portions of the aforementioned rejection appears to be set forth in facts within the personal knowledge of the Examiner and therefore Applicant believes MPEP 2144.03 will apply. Pursuant to MPEP 2144.03, Applicant respectfully requests the Examiner to provide support for his assertion either by an affidavit or by references brought to the Applicant's attention. Otherwise, Applicants request this rejection be removed. *See, e.g.,* MPEP 2143.01

Applicant requests removal of the obviousness rejection of claims 27 and 75.

G. Conclusion

Applicant submits that the claims are in condition for allowance. Favorable reconsideration is respectfully requested.

If any extension of time is required, Applicant hereby requests the appropriate extension of time. Applicant has submitted a fee authorization form for fees associated with a Request for Continued Examination. If any further fees are required, or have been overpaid, please appropriately charge, or credit, those fees to Meyertons, Hood, Kivlin, Kowert & Goetzel, P.C. Deposit Account Number 50-1505/5838-01801/EBM.

Respectfully submitted,

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